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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/597,980

08/15/2006

Jorn Borgert

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PHILIPS INTELLECTUAL PROPERTY & STANDARDS

P.O. BOX 3001

BRIARCLIFF MANOR, NY 10510

EXAMINER

GUPTA, VANI

ART UNIT

PAPER NUMBER

3768

MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/597,980	Applicant(s) BORGERT ET AL.	
	Examiner VANI GUPTA	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/27/2006</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. ***Claims 3 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.***

Claim 3 is vague and indefinite for not clearly indicating what the applicant means by “at least one of the catheter elements can be fixed in a surrounding vessel.” Examiner is unsure as to what manner a catheter element may be “fixed” to the vessel.

Regarding Claim 6, a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c).

Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

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In the present instance, Claim 6 recites the broad recitation “*localizers [are] arranged such that they are at a distance of less than 10 cm,*” and the claim also recites “*at a distance...preferably less than 5 cm,*” which is the narrower statement of the range/limitation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1 – 8 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Twiss et al. (US 5,375,596).

Regarding claims 1 and 2, Twiss et al. (hereafter Twiss) a first catheter element – a *catheter assembly (30)*, and a second catheter element – a *guidewire assembly (22)*, wherein the first and the second catheter element are coupled in such a manner that a sliding movement relative to each other is possible. That is, the guidewire assembly is fitted so that it can be inserted and removed from the catheter (*col. 4, lines 1 – 8 and lines 32 - 47*), thereby inherently creating a sliding action between the two assemblies.

Regarding claims 1 and 4, Twiss also discloses first and second active localizers, such that the first localizer is placed on the catheter assembly, so that the catheter’s spatial position can be determined with at least a second active localizer placed on it, whose spatial position can be determined. A *transmitter/detector unit (2)*, which is common to both the catheter and guidewire, comprises a housing unit with an antenna (**14**) that transmits a RF alternating current

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(AC) signal to the each the antenna(s) that is/are attached to each the catheter and guidewire (*col. 4, lines 16 – 23*). The RF AC signal transmits a magnetic field that is detected by either of the guidewire antennna(s) and/or catheter antenna(s) (*col. 6, lines 50 – 65*).

Regarding Claim 3, in light of the aforementioned 35 U.S.C. 112 second paragraph rejection, Examiner relies on the specification (Page 3, lines 10 – 14) to interpret the term “fixed.” Page 3, lines 10 – 14, refer to “fixing” as positioning one of the catheter elements so that “it cannot move in relation to the vascular system, [so that] the movement of the other catheter element relative to the vascular system [can be observe].”

For purposes of examination, Examiner interprets this to mean that one of the catheter elements is situated in a vessel in such a way that allows the one to slide, move, or remove the second catheter element as desired. Twiss explains that his catheter is designed so that it is capable of being fixed in a surrounding vessel, such that the guidewire may be removed from the vessel while the catheter stays in place (*col. 9, lines 26 – 41*).

Regarding Claim 5, Twiss explains that his guidewire comprises antenna(s) that is/are capable of “radiat[ing]” an RF AC magnetic field (*col. 13, lines 5 – 8*).

Regarding Claim 6, in light of the aforementioned 35 U.S.C. 112 second paragraph rejection, Examiner relies on the specification to determine criticality of the arranging the localizers such that they are at a distance of preferably less than 5 cm from each other during the use of the catheter system. On page 4, lines 1 – 6, Applicants discuss that “the distance between the localizers does not exceed [a] top limit, so that they are exposed to external influences to an almost equal extent. When measuring the relative positions of the two localizers, therefore, the corresponding influences balance each other, reducing them to an insignificant factor.”

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For purposes of examination, examiner interprets this to mean that the localizers must be close enough or far enough from each other, so that they don't cancel each other out during tracking of the catheter elements. Twiss explains that a fine wire antenna, for tracking purposes, may run along the entire length of both the catheter elements. Therefore, the localizers are close enough to each other so that Twiss's system is capable of performing within the limitations of this claim.

Regarding claims 7, 8, and 10, Twiss also discusses method(s) for performing catheter navigation, using the aforementioned components, as the limitations of these method claims read on the limitations of the apparatus claims. More specifically, they read on what the components are designed to perform as indicated by the apparatus claims (*please refer to the same passages mentioned above; and col. 7, lines 51 – 58; col. 9, lines 6 – 61*).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. ***Claim 9 is rejected under 35 USC 103(a) as being obvious over Twiss et al. (US 5,375,596) in view of Kucharczyk et al. (US 2006/0074295 A1).***

Regarding Claim 9, Twiss discloses a method for navigating a catheter system in a vascular system, as explained above.

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However, Twiss differs from Claim 9 in that he does not appear to specifically disclose generating an image of the vascular system with the catheter system contained in it, and in that the spatial position of the first localizer relative to the vascular system is determined on this image.

Nonetheless, *Kucharczyk et al. (hereafter Kucharczyk)* teaches imaging methods that can be used to assist in the determination of devices located in within a patient (paragraph [0016]).

Accordingly, Kucharczyk complements the disclosing of Twiss for the fact that *Kucharczyk* actually incorporates Twiss in his teachings of his invention (*paragraph [0006]*) for the purposes of including Twiss' method and apparatus for determining the position of devices such as the aforementioned catheter system.

Therefore, it would have been prima facie obvious to combine Twiss with the teachings of Kucharczyk to include an imaging method to obtain the invention in the instant Claim 9.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure are as follows: *Sachar (US 2004/0019447 A1)* for apparatus and method for catheter guidance and control and method; and *Chui et al. (US 6,538,634 B1)* for apparatus for simulated image-guided surgery.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VANI GUPTA whose telephone number is (571)270-5042. The examiner can normally be reached on Monday - Friday (8:30 am - 5:30 pm; EST).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-2083. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/V. G./

Examiner, Art Unit 3768

/Long V Le/

Supervisory Patent Examiner, Art Unit 3768